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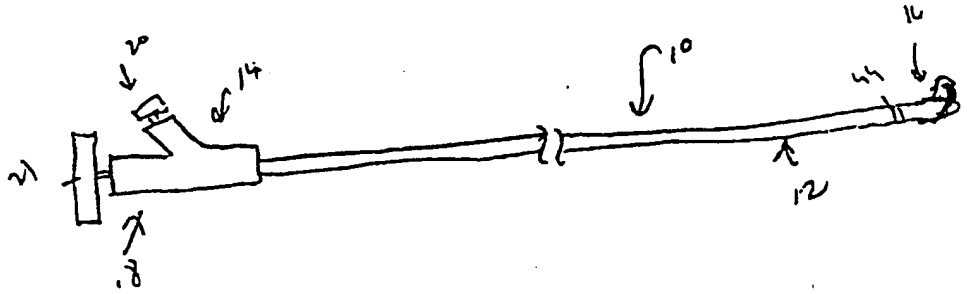
(54) Title: ANEURYSM EMBOLIZATION MATERIAL AND DEVICE



(57) Abstract: The present invention includes a method for treating an aneurysm. The method includes providing a biocompatible polymeric string and transporting the string to an aneurysm. The aneurysm is filled with the string. The string is cut when the aneurysm is substantially filled.

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ANEURYSM EMBOLIZATION MATERIAL AND DEVICE

BACKGROUND OF THE INVENTION

The present invention relates to an aneurysm embolization material and to a method for repairing an aneurysm.

An aneurysm is a balloon-like swelling in a wall of a blood vessel. An aneurysm results in weakness of the vessel wall in which it occurs. This weakness predisposes the vessel to tear or rupture with potentially catastrophic consequences for any individual having the aneurysm. Vascular aneurysms are a result of an abnormal dilation of a blood vessel, usually resulting from disease and/or genetic predisposition which can weaken the arterial wall and allow it to expand. Aneurysm sites tend to be areas of mechanical stress concentration so that fluid flow seems to be the most likely initiating cause for the formation of these aneurysms.

Aneurysm in a cerebral circulation tend to occur in an anterior communicating artery, posterior communicating artery, and a middle cerebral artery. The majority of these aneurysms arise from either curvature in the vessels or at bifurcations of these vessels. The majority of cerebral aneurysms occur in women. Cerebral aneurysms are most often diagnosed by the rupture and subarachnoid bleeding of the aneurysm.

Cerebral aneurysms are most commonly treated in open surgical procedures where the diseased vessel segment is clipped across the base of the aneurysm. While considered to be an effective surgical technique, particularly considering an alternative which may be a ruptured or re-bleed of a cerebral aneurysm, conventional neurosurgery suffers from a number of disadvantages. The surgical procedure is complex and requires experienced surgeons and well-equipped surgical facilities. Surgical cerebral aneurysm repair has a relatively high mortality and morbidity rate of about 2% to 10%.

Current treatment options for cerebral aneurysm fall into two categories, surgical and interventional. The surgical option has been the long held standard of care for the treatment of aneurysms. Surgical treatment involves a long, delicate operative procedure that has a significant risk and a long period of postoperative rehabilitation and critical care. Successful surgery allows for an endothelial cell to endothelial cell closure of the aneurysm and therefore a cure for the disease. If an aneurysm is present within an artery in the brain and bursts, this creates a subarachnoid hemorrhage, and a possibility that death may occur. Additionally, even with successful surgery, recovery takes several weeks and often requires a lengthy hospital stay.

In order to overcome some of these drawbacks, interventional methods and prostheses have been developed to provide an artificial structural support to the vessel region impacted by the aneurysm. The structural support must have an ability to maintain its integrity under blood pressure conditions and impact pressure within an aneurysmal sac and thus prevent or minimize a chance of rupture. U.S. Patent No. 5,405,379 to Lane, discloses a self-expanding cylindrical tube which is intended to span an aneurysm and result in isolating the aneurysm from blood flow. While this type of stent-like device may reduce the risk of aneurysm rupture, the device does not promote healing within the aneurysm. Furthermore, the stent may increase a risk of thrombosis and embolism. Additionally, the wall thickness of the stent may undesirably reduce the fluid flow rate in a blood vessel. Stents typically are not used to treat aneurysms in a bend in an artery or in tortuous vessels such as in the brain because stents tend to straighten the vessel.

Patent No.5,354,295 to Guglielmi et al., describes a type of vasoclusion coil. Disadvantages of use of this type of coil are that the coil may compact, may migrate over time, and the coil does not optimize the patient's natural healing processes.

SUMMARY OF THE INVENTION

One embodiment of the present invention includes a method for treating an aneurysm. The method includes providing a biocompatible polymeric coil, sleeve or hollow string and transporting the string to an aneurysm. The aneurysm is then filled with the coil or string. The coil or string is cut when the aneurysm is substantially filled.

Another embodiment of the present invention includes a kit for treating an aneurysm. The kit includes a biocompatible polymeric string and a catheter for transporting the string to an aneurysm site. The kit also includes a mechanism for cutting the string. The kit optionally includes a biocompatible material for sealing the aneurysm and a balloon for shaping the biocompatible material at the aneurysm neck.

One other embodiment of the present invention includes a biocompatible string, sleeve or coil that comprises a stiff biocompatible core and an outer swellable material, concentrically positioned about the core. A water-soluble material concentrically contacts the outer swellable material and provides a time dependent swelling of the swellable material.

Another embodiment of the present invention includes a method for treating an aneurysm. The method includes providing a biocompatible hollow string or coil and positioning a wire within the hollow string or coil. The wire, string or coil are transported to an aneurysm. The wire is used to guide the string or coil into the aneurysm. The coil, sleeve or hollow string are cut when the aneurysm is substantially filled.

DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of one embodiment of a catheter used for repairing an aneurysm with the method of the present invention.

Figure 2 is a schematic view of one embodiment of delivery of a hydrogel sleeve, coil or string to an aneurysm sac.

Figure 3 is a radial cross-sectional view of one embodiment of the hydrogel sleeve, coil or string of the present invention.

Figure 4 is a side view of a distal tip of a catheter used on the method of the present invention, the tip comprising a mechanism for heating the hydrogel string to terminate the string.

Figure 5a is a side view of one mechanical cutter mechanism for cutting the hydrogel string.

Figure 5b is a side view of the mechanical cutter mechanism of Figure 5a in a closed position.

Figure 6 is a side view of one hollow sleeve, coil, or string embodiment of the present invention positioned proximal to an aneurysm sac.

Figure 7 is a side view of the hollow sleeve, coil, or string embodiment of Figure 6 wherein the hollow sleeve, coil, or string is positioned within the aneurysm sac.

DETAILED DESCRIPTION

One embodiment of the present invention includes a device for sealing and repairing an aneurysm. The device comprises a biocompatible polymeric string, such as is shown schematically at 26 in Figure 2, that is positionable within an aneurysm sac 24 and that functions to fill and then to plug or seal the aneurysm. One biocompatible polymeric string embodiment comprises a hydrogel with drugs and other agents incorporated for healing the aneurysm. A polymeric string embodiment, illustrated in cross-section at 50 in Figure 3, comprises a stiff hydrogel core 52 with a soft hydrogel foam portion 54 that concentrically surrounds the core 52. A gel 56 provides a concentric outer coating or encapsulation of the soft hydrogel foam 54.

The biocompatible polymeric string 26 is, in some embodiments, includes a radiopaque marker such as barium sulfate. The use of the marker enables a physician to determine proper placement and proper fill in the aneurysm sac 24.

The polymeric material 54 is, in one embodiment, a hydrogel foam portion which is swellable and has a swell ratio of 10:1-2:1. The hydrogel foam portion 54 is, for some embodiments, seeded with materials such as growth factors, integrins, cell attachment proteins, cells, and genes and gene products to speed cell overgrowth. The foam provides a desirable surface for rapid cell ingrowth. The hydrogel foam or other filler material is shapable at the aneurysm neck to form a smooth, closed surface at the aneurysm neck.

Swellable materials for use in the present invention include acrylic based materials. For one embodiment, the core material is stiffer

than the outer material, as shown in Figure 3. In particular, Figure 3 shows a cross-sectional area of a material 50 with the core hydrogel 52 and the surrounding foam hydrogel 54. An encapsulation layer 56 covers the foam hydrogel. This layer is gelatin-like and comprises a water dissolvable polymer. The layer, for some embodiments, has a time dependent rate of dissolution. The encapsulation layer is present to prevent premature swelling. The internal core hydrogel 52 may be stiffened as a consequence of an increased degree of cross-linkage as compared to the outer foam hydrogel 54, forming an outer jacket. In another embodiment, the core of the hydrogel string is a soft core metal wire.

The material is fabricated to form a long, continuous cylinder with a core surrounded by a jacket of soft, swellable hydrogel coated with a water soluble material, such as gelatin or other substance to prevent premature swelling. The material is placed into an aneurysm in a continuous fashion until angiographic filling is achieved. The material is then cut or detached . The encapsulation layer dissolves and allows the outer jacket material to swell to a much greater filling volumes than are possible with GDC coils.

While a hydrogel is described, it is understood that other biocompatible, swellable materials are suitable for use in the present invention. Other materials include cellulose acetate, ethylene vinyl alcohol copolymers, polyacrylonitrile, polyvinylacetate, cellulose acetate butyrate, nitrocellulose, copolymers of urethane/carbonate, copolymers of styrene/maleic acid, or mixtures thereof. In particular, it is contemplated that a hydrogel/polyurethane foam is usable in the sleeve, coil or string of the present invention.

Another embodiment of the biocompatible sleeve, coil, or string of the present invention comprises a polymer-based, coil-like structure that is fabricated with soft biocompatible polymers such as ePTFE, urethanes, polyolefins, nylons and so forth, such as is shown at 60 in Figures 6 and 7. Sleeve or coil embodiments include hollow coils such as 60. String embodiments include solid strings and hollow strings. The sleeve, coil or string is fabricated by direct forming, machining, laser cutting, injection molding or coiling/braiding.

These string structures are also capable of fabrication with biodegradable materials such as PLA, PGA, PLGA, polyanhydrides and other

similar biodegradable materials. A use of biodegradable materials provokes a wound healing response and concomitantly eliminates a mass effect of the filled aneurysm over time.

The biocompatible polymeric sleeve, coil or string 26 is deployed to an aneurysm sac 24 through a lumen, illustrated at 12 in Figure 2, which is disposed within the aneurysm sac 24. The lumen 12 is a component of a catheter, such as is illustrated at 10 in Figure 1. The stiff polymer core 52 is guided at 21 of the catheter. In another embodiment, the sleeve, coil or string is pre- fabricated and is guided at 20 or 21 of the catheter. In one other embodiment, a core wire, soft noble metal, gold, platinum, silver, etc. is used instead of the stiff polymer core to make the string.

In another embodiment, illustrated in Figures 6 and 7, a hollow sleeve or coil 60 or a, which is not shown, is transported to an aneurysm sac with a catheter 10. The hollow coil 60 or hollow string is delivered into an aneurysm sac 62 over a wire 64 which is positioned within the aneurysm sac. The coil 60 or hollow string is delivered over the wire 64 and is positioned within the aneurysm 62 without requiring the catheter to enter the aneurysm.

Some embodiments of the polymer sleeve or coil 60 or string comprise a foam component. These embodiments also include cellular growth factors, genes, gene products and drugs within the foam or as a coating on the foam. These embodiments promote healing and repair of the aneurysm.

The sleeve, coil 60 or string is detachable either at the catheter tip or outside in small pushable sections. This embodiment does not require the catheter tip to enter the aneurysm, although the tip may enter the aneurysm. The wire essentially gains access and also functions as a rail to guide the polymer coil 60 or hollow string into the aneurysm. The wire 64 imparts strength and support sufficient to permit the coil or string to be pushed into the aneurysm without the material itself being required to have that support "built-in."

In another embodiment, the coil surface is modified to have an activated coating which causes the coils to bond, adhere or glue together. The modification may be biologic such as a fibrinogen activated surface or may be fabricated by standard chemical techniques. The surface could be made to be self adhesive and surface activatable, as well. This modification secondarily

anchors the coils together prior to an in-growth of cells to complete aneurysmal healing.

The present invention also includes a method for sealing and repairing an aneurysm. The method comprises providing a swellable biocompatible polymeric string. Also provided is a catheter, such as is shown at 10 and Figure 1, that comprises a lumen 12 having a proximal 14 and a distal end 16. The proximal end 14 comprises a manifold 18 with a port 24 for insertion of the biocompatible polymeric string. The biocompatible polymeric string is pushed through the lumen 12 to the distal end 16. The distal end 16, in one embodiment, terminates in a curved tip 22. The curved tip 22 is positionable within an aneurysm sac 24 as is shown in Figure 2.

The biocompatible polymeric string may be detached with a heater, such as is shown at 30 in Figure 4 or cut with a mechanical cutter, shown at 40 in Figures 5a and 5b, located at the distal end 16 of the lumen. In the embodiment in Figure 4, the string 26 is detached with a heater which may be an electrical-based heater or a laser 30.

In another embodiment illustrated at 40 in Figures 5A and 5B, the hydrogel string 26 is cut with a mechanical loop cutter 42. The loop cutter 42 may be manipulated in order to decrease the loop in diameter and cut through the polymer material 26.

The lumen 12 of catheter 10 has a generally circular cross-sectional configuration with an external diameter in a range of about 0.01 to 0.5 inches for cerebral vascular applications. The lumen 12 has sufficient structural integrity to permit the catheter 10 to be advanced to distal arterial locations without buckling or undesirable bending of the lumen 12.

In one embodiment, the distal tip 16 of the lumen includes a marker band 44. The marker band is radiopaque and may be made from materials such as platinum, gold, tungsten, rhenium alloy and alloys of these materials.

It will be understood that the embodiments of the present invention which have been described as illustrative of some of the applications of the principles of the present invention. Various modifications may be made

by those skilled in the art without departing from the spirit and scope of the invention.

IN THE CLAIMS

What is claimed is:

1. A method for treating an aneurysm, comprising:
providing a biocompatible polymeric sleeve, string or coil;
transporting the sleeve, string or coil to an aneurysm;
filling the aneurysm with the sleeve, coil, or string; and
cutting said string.

2. The method of claim 1 and further comprising shaping the sleeve, string or coil to form a compressed sphere-like shape or a torus or a cylinder or a football-shape.

3. The method of claim 1 and further comprising adding cell growth factors to the string.

4. The method of claim 1 wherein the string comprises a hydrogel.

5. The method of claim 1 and further comprising providing a an aneurysm filler.

6. The method of claim 5 and further comprising shaping the filler to form a seal.

7. The method of claim 1 wherein the string is cut with a loop cutter.

8. The method of claim 1 wherein the string is cut with a laser cutter.

9. The method of claim 1 wherein the string is cut with heat.

10. A kit for treating an aneurysm, comprising:
a biocompatible polymeric sleeve, string or coil;

a catheter for transporting the string to an aneurysm site; and

a mechanism for cutting the string.

11. The kit of claim 10 wherein the biocompatible polymeric string comprises a hydrogel, other polymers, and biopolymers.

12. The kit of claim 11 wherein the string comprises a stiff hydrogel core.

13. The kit of claim 11 wherein the string comprises a hydrogel foam.

14. The kit of claim 10 wherein the cutting mechanism comprises a laser cutter.

15. The kit of claim 10 wherein the cutting mechanism comprises a loop cutter.

16. The kit of claim 10 wherein the cutting mechanism comprise a heat-based cutter.

17. A biocompatible sleeve, string or coil, comprising:

a stiff core; and

a foam contacting the core, positioned concentrically about the core.

18. The biocompatible string of claim 17 wherein the stiff core comprises a hydrogel.

19. The biocompatible string of claim 17 wherein the stiff core comprises a wire.

20. The biocompatible string of claim 17 wherein the foam comprises a foam.

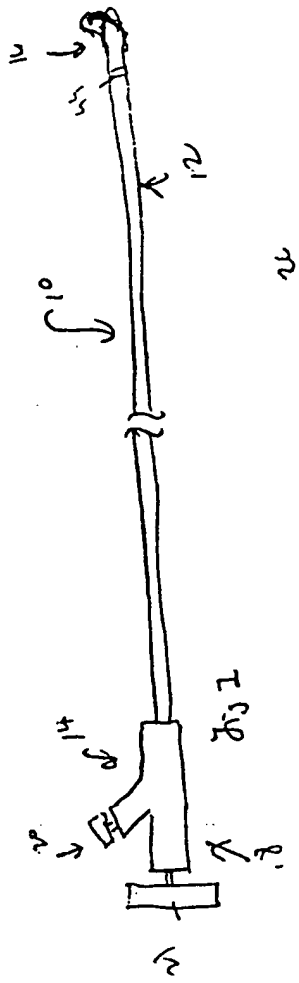
21. The biocompatible sleeve, coil or string of claim 17 and further comprising a water soluble layer that overlays the foam.

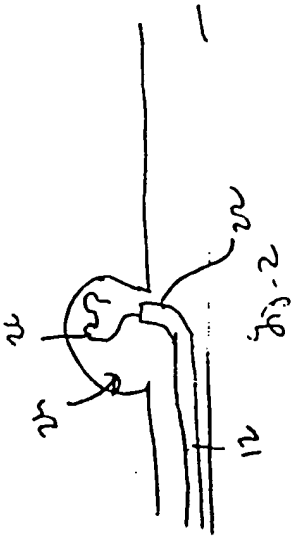
22. The biocompatible string of claim 21 wherein the water soluble layer comprises gelatin.

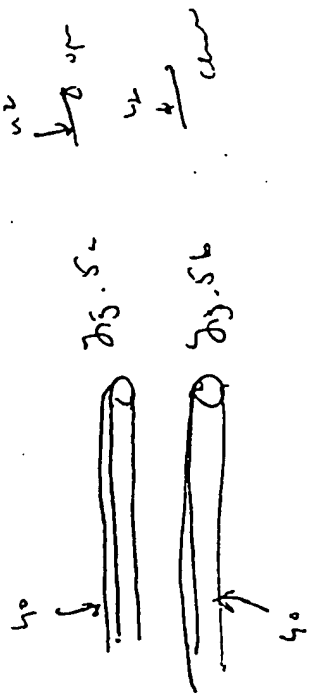
23. The biocompatible string of claim 17 and further comprising cellular growth factors or genes, or gene products or drugs in and on the foam.

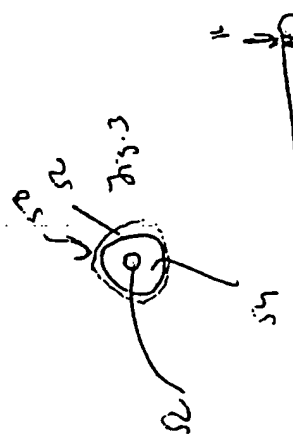
24. A biocompatible sleeve, coil or string made from biodegradable materials.

25. A method for treating an aneurysm, comprising:
providing a biocompatible hollow sleeve, string or coil;
positioning a wire within the hollow string or coil;
transporting the hollow string or coil and wire to an aneurysm; and
using the wire to guide the hollow string or coil into the aneurysm.









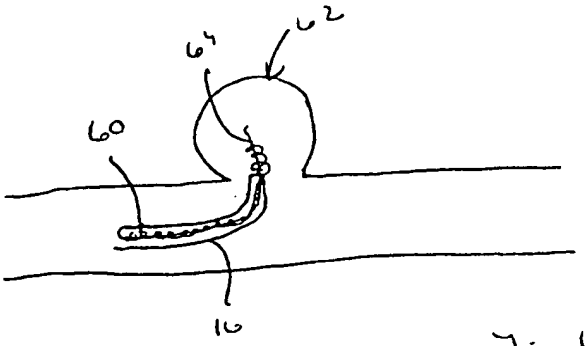


Fig. 6

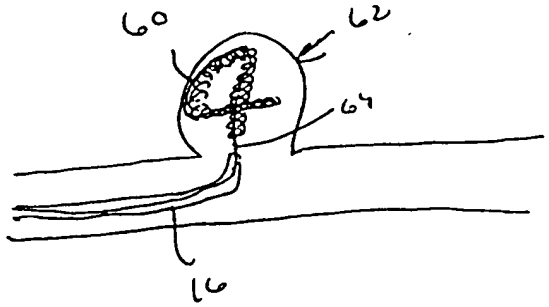


Fig. 7